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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,679

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,679	Applicant(s) PASTERNAK ET AL.	
	Examiner ROBERT LANDSMAN	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6 and 8-13 is/are allowed.
- 6) ☒ Claim(s) 7-14 and 19 is/are rejected.
- 7) ☐ Claim(s) 18 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/27/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A phone call was placed to Dr. Hunter-Ensor on December 1, 2008 to discuss minor issues. However, Dr. Hunter was unable to be reached. Therefore, an Office Action with the following issues is being mailed to Applicants.

1. Formal Matters

- A. The Amendment filed 10/27/08 has been entered into the record.
- B. Claims 1-16 and 18-21 are pending. Claim 21 is withdrawn as being drawn to a non-elected invention. Claim 20, which is not withdrawn as seen by the status identifier (i.e. Original) is being withdrawn by the Examiner since it depends from withdrawn claim 21. Therefore, claims 1-16, 18 and 19 are the subject of this Office Action.

2. Specification

- A. The objection to the specification has been overcome in view of Applicants' submission of a new Figure 1A. **However**, it is noted that this new Figure is labeled "(Sheet 1 of 26)" whereas no other Figures are labeled as such.

3. Claim Objections

- A. All claim objections have been withdrawn in view of Applicants' amendments.
- B. Claim 18 is objected to since it depends from canceled claim 17.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. The rejection of claims 14-20 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims.

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5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendments to the claims.

B. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is confusing, though the Examiner is open to arguments from Applicants. The claim recites a polypeptide selected from the group consisting of SEQ ID NO:51, 53, 55, 57, 59 and 61. However, it then states that the polypeptide is a heterodimer. It is believed that the heterodimer must consist of at least two polypeptides of SEQ ID NO:51, 53, 55, 57, 59 and 61. However, it is not clear if Applicants intend for the claim to cover other polypeptides, in which the recited group does not "consist," or if the heterodimer consists of two or more polypeptides selected from SEQ ID NO:51, 53, 55, 57, 59 and 61. Furthermore "a polypeptide" is singular. Therefore, it is also unclear how the polypeptide could be a homodimers or heterodimer which both comprise a plurality of polypeptides.

The claim could be amended to, for example, "A homodimers or heterodimer consisting of two or more polypeptides selected from the group consisting of SEQ ID NO:51, 53, 55, 57, 59 and 61" if this is what Applicants intend.

C. Claims 14-16 and 19 are confusing since it appears that the same cell is being contacted with both a composition and an opioid. Most assays use two populations of cells to measure two different compounds/events. In other words, one population of cells would be contacted with a test compound and a second population of cells would be contacted with an opioid and both populations compared to a control. Respectfully, when most assays are performed the cells are destroyed or otherwise unusable so the use of another ligand/compound would be expected to be effective. The claims, as written may, in fact, be what Applicants intend. The Examiner only asks clarification.

6. Conclusion

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A. Claims 1-6 and 8-13 are allowable.

B. Non-elected claim 21 and its dependent claim 20 would need to be canceled upon allowance of the elected claims. Claims 20 and 21 may be rejoined under *In re Ochiai* if they meet all of the criteria for patentability including the requirements of 35 USC 101, 102, 103 and 112.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647